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[Docket No. 80N-0451]

**Bacterial Vaccines and Toxoids; Blood
and Blood Derivatives; Availability of
Final Reports of Advisory Review
Panels**

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces the availability of the final report of the Panel on Review of Bacterial Vaccines and Toxoids and the final report of the Panel on Review of Blood and Blood Derivatives.

ADDRESS: Requests for a copy of the final reports may be sent to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Bureau of Biologics (HFB-620), Food and Drug Administration, 8600 Rockville Pike, Bethesda, MD 20205, 301-443-1305.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability to the public of the final reports of the Panel on Review of Bacterial Vaccines and Toxoids and the Panel on Review of Blood and Blood Derivatives, as submitted to the Commissioner of Food and Drugs in accordance with § 601.25(e) (21 CFR 601.25(e)) of the biologics regulations. FDA has released these two panel reports to the Public Citizen Health Research Group (HRCG), a consumer research and advocacy organization. So that other interested persons may have an equal opportunity for the review of these reports, FDA is announcing their availability to the public.

These final reports are currently under review within the agency, and the release of these reports to the public should not be considered as representing FDA's endorsement or approval of the respective panels' findings and recommendations. FDA's response to each panel report, including any proposed actions or disagreements with, or variances from, specific panel recommendations will be published in the Federal Register at a later date in a "Proposed Implementation of Efficacy Review" for each panel report. FDA requests that comments on the panels' reports be withheld until requested in the respective implementation proposal.

Persons interested in obtaining a copy of the panels' reports may write the Dockets Management Branch, Food and Drug Administration, at the address above. Requests should include the docket number found in brackets in the heading of this document and the title of the report being requested; either "Panel on Review of Bacterial Vaccines and Toxoids: Final Report" or "Panel on Review of Blood and Blood Derivatives: Final Report." Appended to each report is a notification that the document is subject to format and editorial changes

prior to publication in the Federal Register. These changes are designed to assure that the document is free of incidental errors and conforms to the stylistic requirements established for documents published in the Federal Register. The reports may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

(FR Doc. 80-36210 Filed 11-20-80; 8:45 am)

BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by James A. Adamson, District Director, Kansas City District Office, Kansas City, MO.

DATE: The meeting will be held at 1 p.m., Wednesday, December 3, 1980.

ADDRESS: The meeting will be held at 1009 Cherry St., Kansas City, MO 64106.

FOR FURTHER INFORMATION CONTACT: Lorena A. Meyers, Consumer Affairs Officer, Food and Drug Administration, 1009 Cherry St., Kansas City, MO 64106, 816-374-3817.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's Kansas City District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: November 13, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

(FR Doc. 80-36211 Filed 11-20-80; 8:45 am)

BILLING CODE 4110-03-M

[Docket No. 80M-0259]

Minnesota Mining and Manufacturing Co.; Premarket Approval of Microbial Profile System

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the

Microbial Profile System (MPS) sponsored by Minnesota Mining and Manufacturing Co. (3M), St. Paul, MN. After reviewing the recommendation of the Immunology and Microbiology Devices Panel, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted label.

DATE: Petitions for administrative review by December 22, 1980.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Henry A. Goldstein, Bureau of Medical Devices (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8162.

SUPPLEMENTARY INFORMATION: The sponsor, 3M, St. Paul, MN, submitted an application for premarket approval of the Microbial Profile System (MPS) (an antimicrobial susceptibility test system) to FDA on September 14, 1979. The application was reviewed by the Microbiology Device Section of the Immunology and Microbiology Devices Panel, and FDA advisory committee, which recommended approval of the application. On July 15, 1980, FDA approved the application by a letter to the sponsor from the Acting Director of the Bureau of Medical Devices.

A summary of the safety and effectiveness data on which FDA's approval is based is on file in the Dockets Management Branch (address above) and is available upon request from that office. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(d)(3)) authorizes any interested person to petition under section 515(e) of the act (21 U.S.C. 360c(e)) for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and of FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of